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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,426	07/02/2001	Kazutoshi Watanabe	P20810	7478

7055 7590 01/04/2005

GREENBLUM & BERNSTEIN, P.L.C.  
1950 ROLAND CLARKE PLACE  
RESTON, VA 20191

EXAMINER
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TRUONG, TAMTHOM NGO

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 01/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/787,426

Applicant(s)

WATANABE ET AL.

Examiner

Tamthom N. Truong

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 27,28,30-33 and 35-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 42 is/are allowed.
- 6) ☒ Claim(s) 27,28,30-33 and 35-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

Applicant's amendment of 09-07-04 has been fully considered. The amended claims have overcome the previous rejection of 112/2<sup>nd</sup> paragraph by clarifying the definition of "W". The amended method claim has also overcome the previous rejection of 112/1<sup>st</sup> paragraph by reciting only a method for the treatment of Alzheimer's disease. Finally, the amended compound claims have obviated the previous 103 rejection based on **Spohr et. al.** (US'753 and US'729) by deleting the majority moieties in the definition of R<sup>2</sup>.

However, an update search yields a reference that necessitates the following new ground of rejection.

Claims 1-26, 29, and 34 have been cancelled.

Claims 27, 28, 30-33 and 35-42 are pending.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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1. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. Claims 27, 28, 30-33, 35-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Skulnick et. al.** (J. Med. Chem., 1985, Vol. 28, pp. 1864-1869). Skulnick et. al. disclose two pyrimidinone compounds (#112 & #113) on page 1867, and an intermediate on page 1864 that are homologous to the compounds of the instantly claimed formula (I) with the following substituents:

- i.  $R^2$  is hydrogen or halogen atom;
- ii.  $R^3$  is 4-pyridyl;
- iii.  $R^1$  is  $-N(R^4)-W-R^5$ ;
- iv. W is a single bond;
- v.  $R^4$  is a hydrogen atom, thus,  $R^1$  is reduced to  $-NHR^5$ .

The disclosed compounds differ from those claimed herein by having  $-NH_2$  (i.e., a primary amine) at the second position, and not  $-NHR^5$  (i.e., a secondary amine).

However, when the instant  $R^1$  is  $-NHR^5$ , the claimed compounds are the next obvious homologues to the compounds of Skulnick et. al. See *Ex parte Weston et. al.*, 121 USPQ 428. The disclosed compounds can be used as an antiviral agent or an intermediate.

Note, claim 28 still recites a secondary amine even though the alkyl group is substituted. Likewise, claims 38 and 39 also recites a secondary amine when R<sup>1</sup> is *N*-benzylamino group, *N*-phenylamino group, *N*-(3-hydroxypropyl)amino group, etc. Therefore, the compounds recited in these claims are still the next obvious homologues to the compounds of Skulnick et. al.

Therefore, at the time of the invention, it would have been obvious for one skilled in the art to select and make some compounds of the instant formula (I) because one would have expected said compounds to have antiviral activity or be an intermediate. See **In re Dillon** 16 USPQ 2d. 1897, 1923 regarding a prima facie case of obviousness of structurally similar compounds disclosed by a prior art “regardless of the properties disclosed in the inventor’s application”.

#### ***Allowable Subject Matter***

Claim 42 is free of prior art, and thus, is allowable for the following reason:

A search yields the reference of **Borroni et. al.** (US 6,586,441 B2) which discloses analogous compounds for the treatment of Alzheimer’s disease. Although Borroni’s compounds are substituted 2-amino-pyrimidinyl, they do not have an “oxo” group at the 4<sup>th</sup> position on the pyrimidinyl ring. Borroni’s formula (19) is a substituted 2-amino-pyrimidinone; however, it is an intermediate, and therefore is not taught for the treatment of Alzheimer’s disease. Furthermore, the effective filing date of US’441 does not antedate the effective filing date of this application. Thus, it is not a competent prior art.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M-F (10:00-6:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

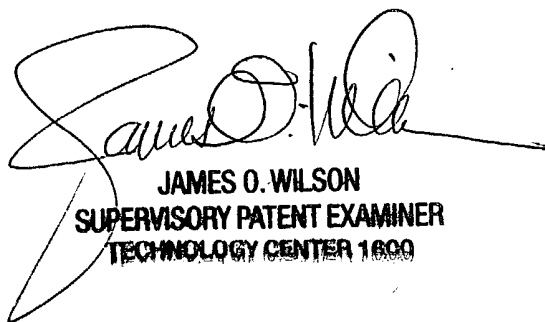
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



**Tamthom N. Truong**  
**Examiner**  
**Art Unit 1624**

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1-3-05



**JAMES O. WILSON**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**